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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,851	03/21/2002	Philippe Msika	REGIM-012	2236

7590 04/07/2006

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EXAMINER

FLOOD, MICHELE C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,851

Applicant(s)

MSIKA ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-87 is/are pending in the application.
- 4a) Of the above claim(s) 65,66,69 and 73-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-64,67,68,70-72 and 76-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 61-85, and the species election of unsaponifiable materials from plant oil, in the reply filed on January 9, 2006 is acknowledged. As Applicant's arguments have been found persuasive, the Office agrees to examine each of the inventions of Groups I and II.

The claims have been examined as far as they read on the elected species.

Claims 61-64, 67, 68, 70-72 and 76-87 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-64, 67, 68, 70-72 and 76-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 61 and 86 recite the limitation "the treatment" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "treatment" with treating.

Claim 61 recites the limitation "the synthesis" in line 8. There is insufficient antecedent basis for this limitation in the claim.

The metes and bounds of Claims 61 and 86 are rendered unclear by the phrase "and increasing the synthesis of skin lipids" because it is unclear as to how the

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functional effect of "increasing the synthesis of skin lipids" is effected. For example, the preamble of the claims is directed to a method of treating a skin condition in a subject comprising the administration of the claim-designated ingredients. However, no process steps is associated with the claim-designated functional effect for "increasing the synthesis of skin lipids". As drafted, it would appear that the claim-designated methods are missing a process step. The lack of clarity renders the claims very vague and ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-64,67,68,70-72 and 76-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Moy (A*).

Applicant claims a method of treating a skin condition of a subject comprising administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillates of plant oil, unsaponifiable materials from plant oil, furan lipids of plants and mixtures thereof to said subjects; and

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increasing the synthesis of skin lipids. Applicant claims a method of treating a skin condition of a subject comprising administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillates of plant oil, unsaponifiable materials from plant oil, furan lipids of plants and mixtures thereof to said subjects; and increasing the synthesis of skin lipids. Applicant further claims the method of claim 86 wherein the composition is a food composition for humans and/or animals and the plant oil product is present in the food composition in a proportion of between about 0.1% and about 20% by weight relative to the total weight of the food composition.

Moy teaches a method of preparing a dermatological composition comprising about 5 and 15 weight percent of unsaponifiable avocado seed lipids, in Column 4, lines 25-37. In Column 3, lines 54-61, Moy teaches that the unsaponifiable material of avocado oil contains sterols (stigmasterol, sitosterol and campesterol). The composition taught Moy are used in the making of topical compositions for the skin, which are used for treating skin keratoses or striae distensae, and eliminating or reducing size of skin lesions. Note that the avocado oil unsaponifiable avocado seed lipids is read herein as a food additive and/or a food composition for humans and/or animals; and, that the food additive taught by Moy is in the same claim-designated amounts of a food additive, as instantly claimed by Applicant. Moy does not expressly teach that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Moy is a one-step process for the administration of a composition comprising

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the same ingredients, and the same amount of the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Moy.

The reference anticipates the claimed subject matter.

Claims 61-64, 67, 68, 70-72, 76, 77 and 80-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamaud et al. (U).

Lamaud teaches a method of treating granuloma in a subject comprising administering an effective amount of a mixture of non-saponifiable fractions of avocado (2/3) and soya-bean (1/3) oils to the skin of the subject. Lamaud further teaches that administration of the unsaponifiable materials of the plant oils increased the level of water, lipids, proteins and collagen in the skin of the treated patient. Note that the mixture of non-saponifiable fractions of avocado oil and soya-bean oil is read as food additive and/or a food composition for humans and/or animals herein. Lamaud further, "The results are in agreement with those obtained using the non-saponifiables taken orally but the effects appear sooner and are localized essentially at skin level."

The reference anticipates the claimed subject matter.

Claims 61-64, 76-78, 80-82 and 84-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Loden et al. (V).

Loden teaches a method of treating dry skin comprising topically administering an effective amount of canola oil and its fraction of unsaponifiable material on sodium

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lauryl sulfate (SLS) irritated skin, which assisted the skin in supplying the damaged skin barrier with adequate lipids. Note that the usaponifiable material of canola oil is read herein as a food additive and/or a food composition for humans and/or animals

The reference anticipates the claimed subject matter.

Claims 61-64, 67, 70 and 76-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Aron-Bruntiere et al. (BJ, FR 2405068).

Aron-Bruntiere teaches the instantly claimed invention. For instance, Aron-Bruntiere teaches topically administering to skin water in oil emulsions comprising an unsaponifiable fraction of plant oil (e.g., avocado oil and soya oil; see Claims 4 and 5 of the patent) containing stigmasterol and alpha-tocopherol. Note that the ingredients avocado oil and soya oil are read herein as a food additive and/or a food composition for humans and/or animals; and, that the food additives taught by Aron-Bruntiere are present in the same claim-designated amounts of a food additives, as instantly claimed by Applicant. The compositions taught by Aron-Bruntiere are applied to conjunctive tissue for the treatment of dry skin conditions, have anti-scleroatrophic action, prevent formation of toxic peroxides, and stimulate renewal of the epidermis and normalizes formation of corneal cells in the sebaceous pores. Aron-Bruntiere does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Aron-Bruntiere is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a

method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Aron-Bruntiere.

The reference anticipates the claimed subject matter.

Claims 61-64, 70 and 76-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Sekimoto et al. (N).

Sekimoto teaches the claimed inventions. For instance, Sekimoto teaches a method of administering an effective amount of a composition comprising sitosterol obtained from various vegetable oils for the treatment of dry skin and keratinization and softening of plantar skin. The composition taught by Sekimoto comprises 0.3% sitosterol or 2.0% of sitosterol-containing vegetable oils. Sekimoto further teaches that the method of administering the referenced composition increases the level of skin lipids in treated patients: "It has become clear from the analytical results of the sebum secreted from the sole of man, that the vegetable sterols including sitosterol are constantly secreted from and present on the young and soft plantar skin and that reducing sugar and amino acids are also secreted therefrom." Note that the ingredient vegetable oil comprising sitosterol is read herein as an unsaponifiable material from plant oil and as a food additive and/or a food composition for humans and/or animals; and, that the food additives taught by Sekimoto are present in the same claim-designated amounts of a food additive, as instantly claimed by Applicant. Sekimoto does not expressly teach that that the referenced method for administering the reference composition is effective in each of the instantly claimed skin disease

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conditions. However, the method taught by Sekimoto is a one-step process for the administration of a composition comprising the same ingredients, and the same amount of the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Sekimoto.

The reference anticipates the claimed subject matter.

Claims 61-64, 67, 68, 70-72, 76, 77 and 80-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Robert et al. (W or X: translation of foreign document provided herein).

Roberts teaches a method of orally administering an effective amount of a mixture of the unsaponifiable fractions of avocado seed oil (2/3) and soybean oil (1/3) to a subject bearing induced skin granuloma for treatment of the skin condition. The avocado oil unsaponifiable fraction was mixed with a soybean oil unsaponifiable fraction and compared to stigmasterol. The study showed that ingestion of the unsaponifiable fractions increased the amount of lipid in the skin and also altered the amount of skin collagen. This effect was somewhat similar to that shown by stigmasterol, but the sterol did not increase the skin lipids as greatly as did the avocado-soy unsaponifiable fraction mixture."

The reference anticipates the claimed subject matter

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 61-64, 67,68, 70-72 and 76-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (W or X).

The teachings of Roberts are set forth above. Roberts teaches the instantly claimed method of treating a skin condition in a subject except for wherein the skin condition is dry skin, ichthyosis, acne, xerosis or atopic dermatitis; and, wherein the composition is administered to treat skin that has been subjected to actinic radiation or UV radiation. While the method taught by Roberts is a method of treating granuloma in a subject comprising administering an effective amount of a mixture of the unsaponifiable materials of avocado and soybean oils to the skin of the subject, Roberts teaches that the treatment increased tissue lipids. Thus, it would have been obvious to one of ordinary skill in the art to administer the composition taught by Roberts to a patient suffering from any of the claim-designated skin conditions to provide the instantly claimed methods of treatment because at the time the invention was made it was known in the art of dermatology that each of the claim-designated skin disorders would benefit from a therapeutic treatment comprising the administration of a composition that provided the beneficial functional effects of increasing the levels of lipids in the skin and decreasing the levels of tissue collagen. Thus, at the time the

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invention was made, one of ordinary skill and the art would have been motivated and one would have had a reasonable expectation of success to use the method of treating a skin condition in a subject taught by Roberts to provide treat any of the claim-designated skin conditions because Roberts suggests that the referenced method comprising the administration of effective amounts of a mixture comprising the unsaponifiable plant oil material from avocado oil and soybean oil is useful in restructuring damaged skin and synthesizing the components comprising the epidermal skin barrier.

Therefore, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
April 1, 2006